[10123/03203]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s)	:	Marcia Wise et al.
Serial No.	:	09/864,488
Filing Date	:	May 24, 2001
For	:	ANTI-CLOTTING METHODS AND APPARATUS INDWELLING CATHETER TUBES
Group Art Unit	:	3763
Examiner	:	Sirmons, Kevin C.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR 3.73(b)

S I R:

SCIMED LIFE SYSTEMS, INC. hereby states that it is the assignee of the entire right, title, and interest of the above-identified application.

An assignment from Catheter Innovations, Inc. to Scimed Life Systems, Inc. was filed separately in the above-identified patent application with the United States Patent and Trademark Office on even date. A copy of the Assignment as filed is enclosed.

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Respectfully submitted,

Dated: Sept. 4, 2003

By: _____
Oleg F. Kaplun, Reg. No. 45,559

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SEPTEMBER 23, 1999

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101101077A

LYNN G. FOSTER
602 EAST 300 SOUTH
SALT LAKE CITY, UT 84102

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

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RECORDATION DATE: 07/22/1999

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BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
WISE, MARCIA A.

DOC DATE: 07/01/1999

ASSIGNEE:
CATHETER INNOVATIONS, INC.
3598 WEST 1820 SOUTH
SALT LAKE CITY, UTAH 84104

SERIAL NUMBER: 09345892
PATENT NUMBER:

FILING DATE: 07/01/1999
ISSUE DATE:

TARA WASHINGTON, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

FORM PTO-1595
(Rev. 6-93)
OMB No. 0651-0011 (exp. 4/94)

07-26-1999

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1. Name of conveying party(ies):
Marcia A. Wise

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

2. Name and address of receiving party(ies)

Name: Catheter Innovations, Inc.

Internal Address:

Street Address: 3598 West 1820 South

City: Salt Lake City State: UT ZIP: 8410

Additional name(s) & address(es) attached? ☐ Yes ☒ No

3. Nature of conveyance: 7-22-99

☒ Assignment ☐ Merger

☐ Security Agreement ☐ Change of Name

☐ Other

Execution Date: July 1, 1999

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s)
09/345,892

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Lynn G. Foster

Internal Address:

Street Address: 602 East 300 South

City: Salt Lake City State: UT ZIP: 84102

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41).....$ 40.00

☐ Enclosed

☒ Authorized to be charged to deposit account

8. Deposit account number:
06-1620

(Attach duplicate copy of this page if paying by deposit account)

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9. Statement and signature.
To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy the original document.

Lynn G. Foster
Name of Person Signing

Signature

7-19-99
Date

Total number of pages including cover sheet, attachments, and document: 4

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents & Trademarks, Box Assignments

ASSIGNMENT

I, Marcia A. Wise of 11551 South Heatherberry Circle, Draper, Utah 84020 and H. Robert Moorehead of 1694 East 5685 South, Salt Lake City, Utah 84121 have invented a ANTI-CLOTTING METHODS AND APPARATUS FOR INDWELLING CATHETER TUBES, hereinafter called the "invention."

Preferred embodiments of said invention are disclosed in a United States Patent Application heretofore executed by me and now identified as File No. 7733 of Lynn G. Foster, Patent Attorney, (U.S. Patent Office Registration No. 21,189), and filed in the United States Patent Office as Serial No. 09/345,892 on July 1, 1999. (I hereby authorize Lynn G. Foster to insert said serial number and filing date when known.)

The Assignee, CATHETER INNOVATIONS, INC., desires to secure the entire right, title, and interest in said invention.

In consideration of $1.00 and other good and valuable consideration paid to me by the Assignee, the receipt and sufficiency of which I hereby acknowledge, I HEREBY ASSIGN TO THE ASSIGNEE:

> The entire right, title, and interest in said invention and in the above-identified United States Patent Application and in all divisions, continuations, and continuations-in-part of said application, or reissues or extensions of Letters Patent or Patents granted thereon, and in all corresponding applications filed in a receiving office of the Patent Cooperative Treaty (PCT) and in regions and countries foreign to the United States, and in all patents issuing thereon in the United States and foreign countries.
>
> The right to file, prosecute, and exclusively own all PCT and foreign patent applications on said invention in its own name, wherever such right may be legally exercised, including the right to claim the benefits of the International Convention and the PCT for such applications and to file, prosecute, and exclusively own all regional applications relating to the invention.

I hereby authorize and request the United States Commissioner of Patents and such Patent Office officials in foreign countries as are duly authorized by their patent laws to issue patents, to issue any and all patents on said invention to the Assignee as the owner of the entire interest, for the sole use and behoof of the said Assignee, its successors, assigns, and legal representatives.

I hereby agree, without further consideration and without expense to me, to sign all lawful papers and to perform all other lawful acts which the Assignee may request of me to make this Assignment fully effective, including, by way of example but not of limitation, the following:

> Prompt execution of all original, divisional, substitute, reissue, and other United States, PCT, and foreign patent applications on said invention, and all lawful

documents requested by the Assignee to further the prosecution of any of such patent applications.

Cooperation to the best of my ability in the execution of all lawful documents, the production of evidence, and the giving of testimony in interference, opposition, nullification, reissue, extension, infringement, or like proceedings involving said invention in any country.

This Assignment and agreement shall be binding upon my heirs and legal representatives.

Marcia A Wise

MARCIA A. WISE

STATE OF UTAH)
: ss.
COUNTY OF SALT LAKE)

On July 1, 1999, before me personally appeared MARCIA A. WISE known to me to be the person described and who signed the annexed Assignment in my presence and acknowledged under oath before me that she has read the same and knows the contents thereof and that she executed the same as her free act and deed and for the purposes set forth therein.

Notary Public
LESLIE K. HINTZ
602 East 300 South
Salt Lake City, Utah 84102
My Commission Expires
December 29, 2002
State of Utah

NOTARY PUBLIC

[SEAL]

H. ROBERT MOOREHEAD

STATE OF UTAH)
: ss.
COUNTY OF SALT LAKE)

On July 1, 1999, before me personally appeared H. ROBERT MOOREHEAD known to me to be the person described and who signed the annexed Assignment in my presence and acknowledged under oath before me that he has read the same and knows the contents thereof and that he executed the same as his free act and deed and for the purposes set forth therein.

Notary Public
LESLIE K. HINTZ
602 East 300 South
Salt Lake City, Utah 84102
My Commission Expires
December 29, 2002
State of Utah

NOTARY PUBLIC

[SEAL]

1999\CATHETER\7733.ASN

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR	Docket Number (Optional) 7733

Applicant or Patentee: MARCIA A. WISE, H. ROBERT MOOREHEAD

Serial or Patent No.: _____

Filed or Issued: FILED HEREWITH

Title: ANTI-CLOTTING AND APPARATUS FOR INDWELLING CATHETER TUBES

As below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

[x] the specification filed herewith with title as listed above.

[ ] the application identified above.

[ ] the patent identified above.

I have not assigned, granted, conveyed or licenses and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

[ ] No such person, concern, or organization exists.

[x] Each such person, concern or organization is listed below.

Catheter Innovations, Inc.
3598 West 1820 South
Salt Lake City, Utah 84104-4959

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Marcia A. Wise	H. Robert Moorehead	
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Marcia A Wise	H Robert Moorehead	
Signature of inventor	Signature of inventor	Signature of inventor
7/1/99	7-1-99	
Date	Date	Date

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(c))--SMALL BUSINESS CONCERN

Docket Number (Optional)
7733

Applicant or Patentee: MARCIA A. WISE, H. ROBERT MOOREHEAD
Serial or Patent No.: _____
Filed or Issued: FILED HEREWITH
Title: ANTI-CLOTTING METHODS AND APPARATUS FOR INDWELLING CATHETER TUBES

I hereby declare that I am

[ ] the owner of the small business concern identified below:
[x] an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN: Catheter Innovations, Inc.
ADDRESS OF SMALL BUSINESS CONCERN: 3598 West 1820 South
Salt Lake City, Utah 84104-4959

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

[x] the specification filed herewith with title as listed above.
[ ] the application identified above.
[ ] the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention must file separate verified statements averring to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization having any rights in the invention is listed below:

[x] no such person, concern, or organization exists.
[ ] each such person, concern or organization is listed below.

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: H. Robert Moorehead
TITLE OF PERSON IF OTHER THAN OWNER: President
ADDRESS OF PERSON SIGNING: 1694 East 5685 South
Salt Lake City, Utah 84121

SIGNATURE: H. Robert Moorehead DATE: 7-1-99

1999\CATHETER\7733DEC.SBC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	)		
	)		
MARCIA A. WISE, ET AL.	)	Docket:	7733.D1
	)		
Serial No.: 09/648,718	)	Art Unit:	3763
	)		
Filed: August 25, 2000	)	Examiner:	KEVIN C. SIRMONS
	)		
For: ANTI-CLOTTING METHODS AND APPARATUS FOR INDWELLING CATHETER TUBES	)		

DECLARATION OF JOHN M. HOLMAN, M.D., Ph.D.

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

State of Utah)
: ss
County of Salt Lake)

Under penalty of perjury, I, John M. Holman, M.D., Ph.D., declare as follows:

1. I am a citizen of the United States of America and a resident of the State of Utah.

2. I am competent to provide the testimony contained in this Declaration.

3. I am a general surgeon and a transplantation surgeon at the University of Utah, Department of Surgery. I have been involved in the practice of medicine for over twenty years, where I enjoy an associate professorship of surgery. I am thoroughly familiar with the use of catheters in the cardiovascular system of medical patients.

4. My Curriculum Vitae is attached as Exhibit "A."

5. Clotting in indwelling catheter tubes has been a long standing problem for which, until the present invention, a satisfactory solution was not found. By way of example only, when I was a surgical intern in 1977-1978, I became familiar with the problem of clotting in open dialysis

catheter tubes while idle between times of use in dialysis of kidney patients. There was then and continued thereafter to be a serious unsolved problem.

6. I was asked to evaluate the Office Action mailed January 17, 2001 in the above-identified patent application, particularly in respect to the Amendment being filed essentially contemporaneously with this Affidavit.

7. I reviewed and analyzed: (a) the application as filed; (b) the Office Action mailed January 17, 2001; (c) the one reference (Stevens U.S. 5,916,193 ('193), relied upon in respect to § 102, and (d) the above mentioned Amendment.

8. The Applicants focused on a certain problem involved with the prior art. The Background section of the above-identified patent application identifies with a measure of specificity the problem addressed by the present Applicant, i.e.:

See pages 1 and 2 of the present application, where it is stated:

> It is desirable to limit the number of times a vessel of the patient is penetrated for placement therein of dialysis catheter tubes. Accordingly, once placed, it is desirable for the distal end of the egress and ingress catheter tubes to be left indwelling for an extended period of time to accommodate spaced, repeated dialysis. Accordingly, the indwelling egress and ingress catheter tubes are inactive typically for much longer intervals than they are active.
>
> * * * *
>
> During idle times, when flow is not occurring in a given indwelling catheter tube, blood tends to enter the distal opening of the indwelling catheter tube . . . During these idle times, blood flow through the vessel around the outside of the catheter tube tends to evacuate liquid from the lumen at the distal tip of the idle indwelling catheter tube, which is replaced by blood. This blood in the distal tip of each catheter tube tends to remain stationary, risking the development of a clot.
>
> When clotting occurs within the lumen at the distal end of a catheter tube, an expensive clot-busting medication, such as Urokinase, is introduced into the proximal end of the catheter tube . . . Sometimes the clot is discharged into the vessel from the lumen using a liquid under positive pressure, which creates undesired risks for the patient. If all else fails, the catheter tube with the clot therein is removed from

the patient at the vessel puncture site and a new replacement catheter tube inserted into the vessel.

9. Basically, Stevens was concerned with expanding a balloon directly against the interior surface of a natural vessel of a medical patient, to occlude blood flow through the vessel, not against a surface of a catheter tube to prevent infiltration of blood into the catheter tube while idle and indwelling. Even when the Stevens balloon is inflated, flow through the tube with which the balloon is associated is accommodated.

10. Stevens states that he and the other co-inventors of the '193 patent were predominantly concerned with "methods preventing blood and other fluids from the heart while the heart is under cardioplegic arrest and the patient is on cardiopulmonary bypass." Col. 1, lines 25-27. Stevens was concerned in doing so "without the open-chest access provided by a median sternotomy or other type of thoracotomy." Col. 2, lines 45-47.

11. Thus, the problem addressed by Stevens was never the prevention of clotting within the interior of one or more catheter tubes when idle and indwelling in the cardiovascular system, which was the basic problem addressed by the above-identified inventors.

12. Among other things, Stevens proposed use of a venting catheter in the following way:

> With the venting catheter in place, the heart rested and cardiopulmonary bypass established, the patient is prepared for a variety of surgical and diagnostic procedures including repair or replacement of aortic, mitral and other heart valves, repair of septal defects, pulmonary thrombectomy, coronary artery bypass grafting, angioplasty, electro-physiological mapping and treatment of aneurysms, transmyocardial revascularization, as well as neurovascular and neurosurgical procedures. Col. 6, lines 1-9.

13. The Stevens disclosure comprises lengthy descriptions of various forms of endovascular partitioning devices. These various embodiments of partitioning devices are illustrated

and described in reference to Figures 25-40, which description begins at Col. 24, line 1 and runs through Col. 35, line 50 and beyond.

14. Because the Examiner relies primarily on the illustrations contained in Figs. 35A and 35B, as well as the descriptive material found in Col. 35, line 5 through 50, this part of the Stevens patent will be analyzed with care. However, preliminary analysis of earlier portions of the Stevens patent will be helpful in understanding the disclosure presented at Col. 35, lines 5-50.

15. Fig. 25 discloses one form of a partitioning device 320. This device also forms a part of the embodiment of Fig. 35A, which further includes a guiding catheter 422 through which part of the partitioning device 320 passes. Before dealing with the guiding catheter 422, the partitioning device 320, best shown in Fig. 25, will be analyzed.

16. Partitioning device 320 comprises an elongated shaft 322, in the form of an elongated tube which comprises a reverse curve at a distal portion 332 (so as to conform to the shape of the aortic arch). An expandable balloon 330 is carried at the distal tip of the shaft 322, which can be deflated or inflated into the configuration illustrated in Fig. 25. The balloon 330 (for expandable means 328) is for "completely occluding the ascending aorta to block systolic and diastolic blood flow." (Emphasized.) Col. 24, lines 10-12.

17. The shaft 322 terminates in a soft distal tip 338, which comprises a central opening 331, which is never closed or occluded and through which a guide wire 342 is adapted to extend.

18. The proximal end 326 of the shaft 322 comprises a triple port adapter 364 providing three ports. Working port 336 is axially aligned with the hollow interior of the shaft 322 and accommodates reception and telescopic advancement of a straightening element 340.

19. Straightening element 340 may be advanced distally into pre-shaped [reverse curved] distal portion 332 so as to straighten the shaft 322, facilitating subcutaneous introduction of

partitioning device 320 into an artery and advancement to the aortic arch. Straightening element 340 may then be retracted proximally relative to the shaft so that distal end 324 can be positioned into the ascending aorta with pre-shaped distal portion 322 conforming to the shape of the aortic arch. Col. 25, lines 52-59.

20. A second port 368 accommodates introduction and removal of a fluid used to inflate and deflate balloon 330. In the configuration of Fig. 25, the fluid insertion and removing device is syringe 370.

21. A third port 372 accommodates measuring of cardiovascular pressure.

22. The guide wire 342, in the embodiment of Fig. 25, loosely passes through a central bore in the straightening element 340 and extends from a position proximal of working port 366, at the proximal end of the shaft 322 through opening 331 at the distal tip 338 of the shaft 322, to assist in placement of the shaft 322.

23. With reference to Figs. 27 and 29A, certain preferred cross sections of the shaft 322 are depicted. More specifically, these embodiments show that the interior of the shaft 322 comprises three longitudinal lumens, i.e., guide wire lumen 329, balloon inflating lumen 346 and pressure sensing lumen 348. Balloon inflating lumen 346 is not in communication with the interior of the cardiovascular system when the shaft 322 is indwelling and the balloon 330 inflated, but the guide wire lumen 329 and the pressure sensing lumen 348 are. Thus, the expansion of the balloon 330 against the vessel wall does not occlude communication to or from the cardiovascular system along lumens 329 and 348.

24. Note further in this regard, the disclosure found at Col. 24, lines 43-49:

> The configuration of the shaped distal portion 332 allows distal segment 334 to be positioned centrally within the lumen of the ascending aorta and distal end 324 to be axially aligned with the center of the aortic valve, thereby facilitating infusion

or aspiration of fluids as well as introduction of surgical tools through opening 331. (Emphasized.)

25. Such infusion, aspiration and surgical instrument introduction would be necessarily along lumen 329 and/or lumen 348 with the balloon 330 inflated. Furthermore, the lumen 329 is used, with the shaft 322 indwelling and the balloon 330 inflated, to deliver cardioplegic fluid to the heart, during the medical procedure mentioned above. Note that ante-graded delivery of cardioplegic fluid is obtained "through first inner lumen 329 . . . to maintain paralysis of the heart, while avoiding undue hemolysis of the blood component (if any) of the fluid." Col. 26, line 67 through Col. 27, line 4. See also Col. 29, lines 36-38.

26. Thus, the interior of the shaft 322 is not occluded with the balloon 330 inflated during the medical procedure of concern to Stevens. See further Col. 27, lines 4-30, and Col. 29, lines 39-42, which indicates passage of not only cardioplegic fluid but saline and/or a contrasting solution as well as aspiration of blood, fluids and debris through lumen 329, all while balloon 330 is inflated against the interior surface of the aortic wall.

27. As further proof that the interior of the shaft 322 is not completely occluded, note Col. 31, lines 3-13 where lumen 329 may accommodate blood flow with the balloon 330 inflated.

28. Figs. 34A and 34B further illustrate the open nature of lumens 329 and 418 of a modified embodiment of the shaft 322, when balloon 330 is inflated against the interior surface of the aorta.

29. The foregoing will be of significant assistance in reviewing the disclosure found at Col. 35, upon which the Examiner relies.

30. It is assumed that the Examiner interprets Col. 35 and Fig. 35A in such a way that the guiding catheter 422 of Stevens is asserting as reading upon the indwelling catheter tube of the claims.

31. The guiding catheter 422 of Fig. 35A comprises an interior lumen 420 (Fig. 35B) which concentrically surrounds the previously described shaft 322 in spaced relation, as best shown in Fig. 35B. The guiding catheter comprises a proximal adapter 428, which defines a first axially-disposed port 430 and a second angularly-disposed port 432.

32. Stevens clearly states "second port 432 [is] in communication with lumen 420 for infusing and aspirating fluid." (Emphasized.) Col. 35, lines 20 and 21.

33. There is no disclosure in Stevens that the central lumen 420 of the guiding catheter 422 is occluded at any time by inflation of balloon 330. Rather, Stevens states: "[b]alloon 330 is then inflated to fully occlude the ascending aorta and block blood flow therethrough." (Emphasized.) See Col. 35, lines 48-50. "Therethrough" means the aorta is occluded, not the distal tip 426 of the guiding catheter 422, since distal end 426 must be left open in order for infusing or aspirating fluid to pass through the second port 432 and the lumen 420 during use of the device of Fig. 35A. See Col. 35, lines 20-21.

34. Even if the distal tip 426 of the guiding catheter 422 were occluded by the balloon 330, which it is not, the entire interior of the guiding catheter is not occluded, since the shaft 322, along lumens 329 and 348 (Fig. 35B), are not. This accommodates liquid communication along the interior of the shaft 322 (and, therefore, along the interior of the guiding catheter 422 during the medical procedure) while the balloon is inflated.

35. A comparison of the positions set forth in the Office Action mailed November 13, 2000 and the disclosure of Stevens, as characterized above, will, it is believed, be helpful. That comparison is presented in columnar form below.

Office Action §102 and §103 Statements	The Stevens' Disclosure
Stevens discloses a method of addressing the problem of clotting in an idle catheter tube	Stevens does not address a problem of clotting in an idle catheter tube but rather addresses the problem of bypass heart surgery in a low invasive way where the catheter tube and/or the shaft are not idle and subject to clotting, but are open and active to accommodate instrument insertion, infusion (including cardioplegic fluid) and aspiration.
advancing a deflated balloon along a hollow interior of the idle indwelling catheter tube to a distal end thereof (col. 35, lines 35-50)	If guiding catheter 422 is considered the claimed catheter tube, the shaft 322 does advance the deflated balloon, but not "to the distal end thereof." Instead the balloon 330 is advanced well beyond the distal end 426 of guiding catheter 422.
inflating the balloon to close and seal the hollow interior at the distal end of the idle indwelling catheter tube to deny blood access to the hollow interior (col. 35, lines 48-50)	Absolutely not. When the balloon is inflated, it is expanded distally beyond the catheter 422 against the wall of the aorta (see the space between catheter distal end 426 and inflated balloon 330) leaving the lumen 420 of the catheter open for aspiration and infusion using also port 432 (Col. 35, line 21).
purging the hollow interior of the catheter tube in a proximal-to-distal direction with a suitable liquid under pressure (col. 35, lines 17-21); wherein the purging act precedes the inflating act (col. 34, lines 5-50)	Infusion and purging are different. There is no disclosure in Stevens of purging, i.e. ridding the interior of the catheter tube of accumulated or residual, unwanted material for a very short time. Furthermore, the position in the Office Action is based on a false assumption, i.e. that the hollow of the catheter tube is occluded by the balloon, by which it is not.
terminating flow along a hollow interior passageway of the indwelling catheter tube; after the terminating act, inflating a balloon to close and seal the hollow interior passageway at a distal end of the indwelling catheter tube to deny blood in the vessel access to the hollow interior (col. 35, lines 35-50)	The interior 420 of catheter 422 is never sealed or occluded by the balloon. The term "aspirating" (Col. 35, line 21) includes withdrawing blood during the procedure. Similarly, "aspiration" occurs through one of the lumens in the shaft 322 (Col. 24, line 47), which is within the interior 420 of the catheter 422. Aspiration of blood, under these conditions, is expressly mentioned at Col. 29, line 41.

it would have been obvious to one of ordinary skill in the art at the time the invention was made to purge the catheter tube after the inflation to flush out any remaining unwanted liquid in the catheter tube.	This erroneous assertion is based on two false premises, i.e. there is purging and catheter occlusion in Stevens. Neither occurs. Furthermore, if the balloon 330 in fact occluded the lumen 420, which it does not, there is no basis in Stevens to conclude that such an occlusion could and should be overridden by purging pressure while the balloon remains inflated.
it would have been obvious to one of ordinary skill in the art to place a distance indica on the catheter for the purpose of tracking movement of the balloon catheter within the catheter tube	This conclusion has no basis in Stevens. To the contrary, Stevens uses one or more radiopaque strips 339 and fluoroscopy "for positioning the balloon 330." Col. 25, lines 34-36.
It would have been obvious to one having ordinary skill in the art at the time the invention was made to duplicate the method as claimed with two or more catheters, i.e. addressing the problem of clotting in idle ingress and egress companion catheter tubes indwelling within a vessel of a medical patient, comprising the acts of: advancing a deflated balloon along a hollow interior of each idle ingress and egress catheter tubes to a distal end of each; inflating the respective balloons to close and seal the hollow interior at the distal end of each catheter tube, thereby denying blood access to the hollow interior of each; comprising the act of purging the hollow interior of one or both catheter tubes in a proximal-to-distal direction with a suitable liquid under pressure; wherein the purging act precedes the inflating act; further comprising the acts of deflating both balloons and causing ingress and egress flow through the respective hollow interiors of the catheter tubes.	These are quantum leaps for which there is no teaching or suggestion in Stevens.

36. From the foregoing, in my opinion, the present invention, as claimed, is not anticipated nor obvious to one of ordinary skill by the Stevens reference.

37. Claims 14, 41 and 42, as earlier constituted, were rejected under 35 USC § 102(e) as anticipated by U.S. Patent No. 5,833,650 ('650), issued to Imran. The Examiner enunciated his position, at page 5, lines 10-16 of the Office Action mailed January 17, 2001 in the following statement:

> Imran discloses a method of addressing the problem of clotting an idle ingress and egress companion catheter tubes indwelling within a vessel of a medical patient, comprising the acts of advancing a deflated balloon along a hollow interior of each idle ingress and egress catheter tube to a distal end of each (col. 5); inflating the respective balloons to close and seal the hollow interior at the distal end of each catheter tube, thereby denying blood access to the hollow interior of each (col. 5 and 6); purging the hollow interior of one of both catheter tubes in a proximal to distal direction across a slit valve with a suitable liquid under pressure (col. 5 and 6).

38. Reliance by the Examiner upon Imran is couched in a measure of ambiguity, since there is no correlation to the numerals used in Imran. Accordingly, it is not clear how the Examiner is interpreting Imran as being anticipatory of Claims 14, 41 and 42, as previously constituted. Notwithstanding this element of uncertainty, as pointed out below, Imran does not stand for the propositions asserted on page 5 of the Office Action mailed January 17, 2001.

39. Unlike the present invention, as set forth in the presently pending claims of the above-identified patent application, Imran does <u>not</u> address the problem of clotting in ingress and egress idle companion catheter tubes. To begin with, the indwelling tubes of Imran are not left idle and indwelling at the end of a medical procedure. Rather, they are inserted, utilized and removed.

40. The catheter assemblies disclosed by Imran are for the purpose of treating stenosis (a.k.a. atheroma or plaque). In other words, the problem addressed by Imran is to restore or enlarge lost blood flow capacity through arteries, due to clogging by use of a procedure akin to balloon angioplasty (Figs. 1-6E) or to sever plaque 76 from the inside of the arterial wall using an atherectomy device 81 (Fig. 7).

41. In respect to Figs. 1-6E, Imran proposed that three concentric tubes be inserted through the aorta 64 (Fig. 5) into the left carotid artery 67. As best seen in Figs. 1-4, these three concentric tubes comprise outside tube 16, intermediate tube 51 and interior tube 31. Each tube is equipped with a balloon at the distal end thereof, i.e., balloon 19, balloon 58 and balloon 36. Outside tube 16 comprises a lumen 22 by which the associated balloon 19 is appropriately inflated and deflated. Tube 51 comprises a balloon inflating lumen 59, by which balloon 58 is inflated and deflated. Tube 31 defines a lumen 39 by which balloon 36 is inflated and deflated.

42. Tube 16 comprises a lumen 26 (Fig. 4) for aspirating blood from a so-called working area 78 (Fig. 6D). Fitting 27 assists in the mentioned aspiration function. See Fig. 1.

43. The interior tube 31 defines not only the previously mentioned balloon inflating lumen 39 but also a second lumen 43 (Fig. 2) through which a guide wire 436 is extended and along which saline is displaced.

44. Note, in respect to Fig. 1, that the balloon 19 is inflated directly against the interior surface of the vessel 14 at a location proximal of the stenosis 12 to be treated. Note also, that the second balloon 36, carried at the distal end of the interior tube 31 is inflated directly against the interior surface of the vessel 14 at a location distal of the stenosis 12 to be treated. Note further, that balloon 58 is used essentially to perform an angioplasty function by being expanded under high pressure to radially displace the stenosis 12 outwardly and thereby increase the size of the flow path through the stenosis 12.

45. Given the foregoing, none of the balloons 19, 36 and 58 are expanded radially against another tube, including a catheter tube, for the purpose of occluding that tube. Rather, the balloons 19 and 36 are expanded contiguously against the vessel and the balloon 58 is expanded against the stenosis 12.

46. In lieu of the angioplasty balloon 58 (Fig. 1), a plaque cutting device, a.k.a. atherectomy device 81 may be used to sever plaque or stenosis from the interior of the vessel 67 thereby increasing the size of the flow path through the stenosis 76. See Fig. 7.

47. It is of significance that flow through interior lumens of the tubes 16, 51 and 31 is not prevented, but rather accommodated during the angioplasty procedure (Fig. 1) or the atherectomy procedure (Fig. 7). Specifically, aspiration of blood from working area 78 along lumen 26 through port 27 is accommodated. This occurs after balloon 19 has been inflated. See Col. 5, lines 35-43.

48. Furthermore, pieces or particles of plaque knocked off from the stenosis deposit "will be drawn out with the reverse flow of blood into the aspirating lumen 26 and out of the aspiration fitting 27." Col. 5, lines 46-51.

49. Advancement of the guide wire 46 is accompanied by introduction of saline solution through the lumen 43 of the inner tube 31. This also aids in the flow of particulate or other particles dislodged from the stenosis during advancement of the guide wire. See Col. 5, lines 51-63.

50. In addition, "blood is shunted across the stenosis . . . and into the lumen 68 distal of the second balloon 36 by introduction of blood through the fitting 38 and into the centrally disposed blood flow lumen 37 in the second tubular member 31 so that it exits out the central lumen 37 distal of the second balloon 36." Col. 6, lines 11-16.

51. Note that aspiration of the working space 78 is on an on-going basis, even after the third balloon (balloon 58) is removed from the stenosis following balloon angioplasty at that location. See Col. 7, lines 2-5.

52. From the foregoing it is abundantly clear that several of the lumens of tubes 16, 51 and 31 remain open during the procedure and none are closed by inflation of balloons 19, 36 and 58.

53. The position set forth in the Office Action mailed January 17, 2001, in respect to Imran, when compared with the disclosures contained within Imran, will, it is believed, be helpful. That comparison is presented in columnar form below:

Office Action § 102 Statements With Respect to Imran	The Imran Disclosure
Imran discloses a method of addressing the problem of clotting in idle ingress and egress companion catheter tubes indwelling within a vessel of a medical patient	Imran does not address a problem of clotting in one or more catheter tubes, but rather addresses treatment of plaque in an artery which partially occludes the vessel. The tubes of Imran do not remain idle and indwelling. Tubes 16, 51 and 31 are removed after the plaque treatment is over.
inflating the respective balloons to close and seal the hollow interior at the distal end of each catheter tube, thereby denying blood access to the hollow interior of each	Imran does not use a balloon to close and seal the hollow interior of any catheter tube. The balloons of Imran expand to close and seal against the vessel wall or plaque deposited on the vessel wall. In Imran no balloon denies blood access to the hollow interior of any catheter tube. Blood flows through lumen 26 after balloons have been inflated. Blood also flows through lumen 37 after balloons are inflated. Therefore, blood access to the hollow interior of each tube 16, 51 and 31 of Imran is not denied by balloon inflation.
purging the hollow interior of one or both catheter tubes in a proximal to distal direction across a slit valve with a suitable liquid under pressure	Imran does not teach purging in a proximal to distal direction, nor does Imran teach purging across a slit valve. In fact, Imran's system does not comprise a slit valve.

54. In my opinion, Imran does not anticipate nor make obvious the presently pending claims of the above-identified application.

55. I have read each of the presently pending claims. None of the terms in the claims are ambiguous to me, nor would they be to one of ordinary skill. Therefore, I believe the claims, as presently constituted, satisfy 35 USC § 112, second paragraph.

56. I hereby declare that all statements made herein are of my own knowledge to be true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED this 27 day of February, 2001

John M. Holman Jr

JOHN M. HOLMAN, M.D., PH.D.

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EXHIBIT A

(Dated: November, 2000)

CURRICULUM VITAE

I. PERSONAL DATA

A. NAME: John M. Holman, Jr., M.D., Ph.D.

B. BUSINESS ADDRESS: University of Utah School of Medicine
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Salt Lake City, UT 84132

(Office #): (801) 581-7508
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(E-Mail): John.Holman@HSC.Utah.Edu

C. DATE OF BIRTH: August 3, 1951

D. PLACE OF BIRTH: Pittsburg, Texas

E. CITIZENSHIP: U.S.A.

F. MARITAL STATUS: Married

G. SOCIAL SECURITY NO.: 466-94-3158

II. EDUCATION

A. B.S. in Natural Sciences (with Honors), 1973, Washington and Lee University, Lexington, Virginia.

B. M.D., 1977, University of Texas Southwestern Medical School, Dallas, Texas.

Ph.D. in Physiology, 1986, Albany Medical College of Union University, Albany, New York.

C. Residency and Fellowship Training:

1977 - 1978	University of Utah School of Medicine, Salt Lake City, Utah, Internship (straight surgery).
1978 - 1979	University of Utah School of Medicine, Salt Lake City, Utah, Surgical Resident.

II. EDUCATION (Cont'd.)

1979 - 1980	University of Utah School of Medicine, Salt Lake City, Utah, General Surgery Research Fellow.
1980 - 1982	University of Utah School of Medicine, Salt Lake City, Utah, Surgical Residency (Chief Resident, 1982).
1982 - 1986	NIH Postdoctoral Fellow and Ph.D. Student, Department of Physiology, Albany, New York.
1985 - 1986	Renal Transplant Fellow, Albany Medical Center Hospital, Albany, New York.
D. Board Certification:	American Board of Surgery, 1983. Recertification: 1993
E. Medical Licensure:	Texas, 1977 Utah, 1978

III. PROFESSIONAL EXPERIENCE

A. Full-time Positions:

1985 to July, 1986	Assistant Professor of Surgery and Assistant Professor of Physiology, Albany Medical College, Albany, New York.

Areas of specialization included general surgery and renal transplantation. Responsibilities were those of assistant attending surgeon at the Albany Medical Center Hospital and coordinator of surgical residency program for department of surgery. Additional responsibilities included participation in clinical pathophysiology correlation lectures and cardiovascular physiology dog laboratory exercises in first year medical physiology course.

July, 1986 to June, 1992	Assistant Professor of Surgery, University of Utah School of Medicine, Salt Lake City, Utah.
July, 1992 to Present	Associate Professor of Surgery, University of Utah School of Medicine, Salt Lake City, Utah.

Areas of specialization include general surgery and renal transplantation. Responsibilities are those of attending surgeon at the University of Utah Hospital.

July, 1992	Award of Tenure, University of Utah School of Medicine, Salt Lake City, Utah.

III. PROFESSIONAL EXPERIENCE (Cont'd.)

B. Part-time Positions:

1987 to Present	Medical Director, Intermountain Organ Recovery System, Salt Lake City, Utah

Duties are to direct and oversee cadaveric organ recovery for the State of Utah and Southeastern Idaho.

C. Editorial Experience: None

D. Research Awards:

Funded:

1985 - 1986	American Society of Transplant Surgeons - Sandoz Research Award from The American Society of Transplant Surgeons, Research Award, Principal Investigator, $25,000.
1986 - 1988	Role of Reticuloendothelial System in the Immune Response to Injected Antigen, University of Utah Research Committee Grant, Principal Investigator, $43,000.
1986 - 1987	Effect of Cyclosporine on Reticuloendothelial Phagocytic Activity, University of Utah Research Committee Grant, Principal Investigator, $5,000.
1988 - 1989	A Prospective Assessment of Quality of Life in Diabetic End-Stage Renal Disease Patients, University of Utah Research Committee Grant, Principal Investigator, $5,000.
1989 - 1990	Role of Fibronectin in Lymphocyte Activation, University of Utah, Research Committee Grant, Principal Investigator, $5,000.
1989 - 1991	Induction Therapy with OKT-3 in Renal Transplant Patients, Ortho Pharmaceutical Company, Principal Investigator, $8,500.
1991 - 1992	Role of Fibronectin in Lymphocyte Activation, University of Utah, BRSG, Principal Investigator, $7,500.

III. PROFESSIONAL EXPERIENCE (Cont'd.)

1991	Evaluation of Rechargeable Biohybrid Pancreas, SBIR, NIH, Consultant, $8,000.
1994 - 1995	A Multiple Intravenous Infusion, Rising Dose Study to Determine the Safety, Tolerability, Pharmacokinetics and Immunologic Effect of Orthoclone OKTcdr4a (RWJ 4004) in Primary Renal Allograft Recipients, Principal Investigator, $68,000.
1995 - 1996	A Multi-Center, Randomized, Double-Blind, Placebo Controlled Trial of SDZ621 for the Prevention of Acute Cellular Rejection in Renal Allograft Recipients, Sandoz Pharm AG, Co-Invetigator.
1997	A Feasibility Study of Seare Matrix Cuffed Peritoneal Catheters, Seare Biomatrix Systems, Inc., Principle Investigator, $5,000.
1997	An Open-Label, Safety, Tolerance and Pharmaco-Kinetic Study of Oral Mycophenolate Mofetil Suspension in the Prophylaxis of Rejection in Pediatric Renal Allograft Recipients, Roche Global Development, Co-Investigator, budget pending.
1999	Creatinine Biosensor for Renal Transplant Monitoring, 581R, NIH, Consultant, $2,640.
2000	A Randomized, Open Label Preference Study of Gengraf Compared to Neoral in Stable Solid Organ Transplant Subjects, Abbott, Co-Investigator.
2000	Single Center, Open Label Study Comparing Thymoglobulin vs. OKT3 for Induction Immunosuppression Therapy in Primary Adult Cadaveric and Living Unrelated Renal Transplant Recipients, Sangstat, Co-Investigator.
2000	Rapamune Protocol 0468E1-100154, Wyeth-Ayerst, Co-Investigator.

III. PROFESSIONAL EXPERIENCE (Cont'd.)

2000	Retrospective Collection of Followup Data in Subjects Participating in Burroughs Wellcome Protocol P66/H73-012, Principle Investigator, $2000.

IV. SCHOLASTIC HONORS

Phi Eta Sigma, 1970, Washington and Lee University
Phi Beta Kappa, 1973, Washington and Lee University
Sigma Xi, 184, Albany Medical College of Union University
Recipient of the Graduate Student Award for Excellence in Teaching in the Graduate Studies Program of Albany Medical College, 1984.
Recipient of the Graduate Studies Program Award for Excellence in Academic Studies of Albany Medical College, 1985.

V. ADMINISTRATIVE EXPERIENCE

Nov. 1985 to July, 1986	Coordinator Surgical Residency Program, Department of Surgery, Albany Medical College, Albany, New York.
Aug. 1986 to July, 1995	Director of Surgical Research, Department of Surgery, University of Utah School of Medicine, Salt Lake City, UT.
July 1987 to June 1988	Chairman, Research Committee, American Diabetes Association Utah Affiliate, Inc.
Oct 1987 to 1993	Member, UNOS Region 5 Organ Procurement and Distribution Committee.
June 1991 to 1992	Member, UNOS Region 5 Ad Hoc Pancreas Transplant Committee.
Jan 1992 to Dec 1993	UNOS Organ Procurement Organization Committee, Region 5 Representative
July 1995 to Present	Medical Director, Dumke Clinic, University of Utah Hospital & Clinics, Salt Lake City, UT.

V. ADMINISTRATIVE EXPERIENCE (Cont'd.)

Oct 1995 to 1997	UNOS Scientific Advisory Committee, Region 5 Representative
July 1996 to July 1998	UNOS Membership and Professional Standards Committee Region 5 Representative
Dec. 1996 to Present	Director, University of Utah Renal Transplant Program, Salt Lake City, UT.
July 1997 to July 1998	Chairman, Data Subcommittee, UNOS Membership and Professional Standards Committee.
July 1998 to July, 2000	Member UNOS Board of Directors, Region 5 Representative

VI. PROFESSIONAL COMMUNITY ACTIVITIES

1986	Chairman, National Kidney Foundation Annual Golf Fund Raiser.
1986 to Present	American Diabetes Association, Utah Chapter, Speakers Bureau.
1992 to 1994	Secretary/Treasurer, Western Association of Transplant Surgeons.
1994 to 1995	President, Western Association of Transplant Surgeons.
1996 to 1998	Member, UNOS Membership & Professional Standards Committee.
1998 to 2000	Counselor, UNOS Region 5. Member, UNOS Board of Directors.
2000 to Present	Member, UNOS Technology Advisory Group.

VII. UNIVERSITY COMMUNITY ACTIVITIES

1987 to Present	Member, General Clinical Research Center Advisory Committee, University of Utah School of Medicine.
1994 to 1997	Member, Institutional Review Board, University of Utah School of Medicine.

Responsibilities of both committees are to review research protocols submitted to utilize the facilities of the University of Utah School of Medicine.

1997 to Present	Member, Electronic Medical Record Committee, University of Utah Hospital & Clinics, Salt Lake City, Ut.
1997 to 1999	Member, Clinical Systems Advisory Committee, University of Utah Hospital & Clinics, Salt Lake City, Ut.
1997 to 1999	Member, Operating Room Information System Advisory Group, University of Utah Hospital & Clinics, Salt Lake City, Ut.
1998 to Present	Member, Capital Budget Committee, University of Utah Hospital & Clinics, Salt Lake City, Ut.
1999 to Present	Member, Regional Outreach Advisory Board, University of Utah Hospital & Clinics, Salt Lake City, Ut.
1999 to Present	Member, Physicians Advisory Panel, University of Utah Hospital & Clinics, Salt Lake City, Ut.
2000 to Present	Member, SMART Committee, University of Utah Hospital & Clinics, Salt Lake City, Ut.
2000 to Present	Member, Technology Assessment Steering Committee, University of Utah Hospital & Clinics, Salt Lake City, Ut.

VIII. MEMBERSHIP IN PROFESSIONAL SOCIETIES

Fellow, American College of Surgeons
American Medical Association
Association of Academic Surgery
American Diabetes Association
The Salt Lake Surgical Society
The Southwestern Surgical Congress
The Western Association of Transplant Surgeons
American Society of Transplantation
The Transplantation Society
American Society of Transplant Surgeons

IX. TEACHING ASSIGNMENTS

1987 to 1996	Medical Immunology (Pathology 6000) - Sophomore Medical School Class, University of Utah (n=100) Lecture: "Clinical Transplantation"
1987 to 1996	Intermediate Critical Care Course, College of Nursing, University of Utah (n=30) Lecture: "Transplantation in the Diabetic Patient"

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I. PUBLICATIONS:

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2. Holman, J.M., Jr., and Rikkers, L.F.: Success of Medical and Surgical Management of Acute Variceal Hemorrhage. Am. J. Surg. 140:816-821, 1980.

3. Holman, J.M., Jr., and Albo, D.: Peritoneojugular Shunting in Malignant Ascites. Am. J. Surg. 142:774-776, 1981.

4. Holman, J.M., Jr., and Rikkers, L.F.: Biliary Obstruction and Host Defense Failure. J. Surg. Res. 32:208-213, 1982.

5. Landes, N., Holman, J.M., Jr., and Maxwell, J.G.: Rehabilitation of End-Stage Renal Disease Patients Through Transplantation. Dialysis and Transplantation 12:580-582, 1983.

6. Saba, T.M., Niehaus, G.D., Scovill, W.A., Blumenstock, F.A., Newell, J.C., Holman, J.M., Jr., and Powers, S.R.: Lung Vascular Permeability After Reversal of Fibronectin Deficiency in Septic Sheep: Correlation with Patient Studies. Ann. Surg. 18:654-662, 1983.

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9. Holman, J.M., Jr., Saba, T.M.: Effect of Bacterial Sepsis on Gluconeogenic Capacity in the Rat. J. Surg. Res. 45:167-175, 1988.

10. Holman, J.M., Jr., Saba, T.M., and Lewis, E.: Effect of Fibronectin-Rich Human Cryoprecipitate on Fluid Resuscitation Requirements During Post-Operative Sepsis. J. Trauma 28:571-581, 1988.

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12. Christensen, A.J., Holman, J.M., Jr., Turner, C.W., and Slaughter, J.R.: Quality of Life in End-Stage Renal Disease: Influence of Renal Transplantation. Clinical Transplantation 3:46-53, 1989.

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14. Christensen, A.J., Turner, C.W., Slaughter, J.R., and Holman, J.M., Jr.: Perceived Family Support as a Mediator of Psychological Well-Being in End-Stage Renal Disease. J. Behavioral Medicine 12:249-265, 1989.

15. Christensen, A.J., Smith, T.W., Turner, C.W., and Holman, J.M., Jr.: Type of Hemodialysis and Preference for Behavioral Involvement. Interactive Effects on Adherence in End-Stage Renal Disease. Health Psychology 9:225-236, 1990.

16. Holman, J.M., Jr., and Todd, R.: Enhanced Survival of Heterotopic Rat Heart Allografts with Portal Venous Drainage. Transplantation 4:229-230, 1990.

17. Christensen, A.J., Turner, C.W., Smith, T.W., Holman, J.M., and Gregory, M.C.: Health Locus of Control and Depression in End-Stage Renal Disease. J. Consult Clin Psychol 59:419-424, 1991.

18. Christensen, A.J., Holman, J.M., Jr., Turner, C.W., Smith, T.W., Grant, M.K., and DeVault, G.A.: A Prospective Study of Quality of Life in End-Stage Renal Disease: Effects of Cadaveric Renal Transplantation. Clinical Transplantation 5:40-47, 1991.

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21. DeVault, G.A., Jr., Kohan, D.E., Nelson, E.W., and Holman, J.M., Jr.: The Effects of Oral Pentoxifylline on the Cytokine Release Syndrome During Inductive OKT3. Transplantation 57(4):532-540, 1994.

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22. Nelson, H.A., Gilfeather, M., Holman, J.M., Nelson, E.W., Yoon, H.C.: Gadolinium-enhanced breathhold three-dimensional time-of-flight renal MR angiography in the evaluation of potential renal donors. Journal of Vascular and Interventional Radiology 10:175-181, 1999.

23. Kriskovich, M.D., Holman, J.M. and Haller, J.R.: Calciphylaxis: Is There a Role for Parathyroidectomy? The Laryngoscope 110(4):603-607, 2000.

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2. Holman, J.M., Jr.: The Role of Fibronectin in Severe Surgical Sepsis. Infections in Surgery 7(2):135-151, 1988.

III. BOOK CHAPTERS

1. Saba, T.M. and Holman, J.M., Jr.: Fibronectin and Phagocytic Host Defense Mechanisms. In: Surgical Care II: A Physiologic Approach to Clinical Management. Ed., R.E. Condon and J.J. DeCosse, Lee & Febiger, Philadelphia, 1985, pp. 271-282.

2. Holman, J.M., Jr., and Rikkers, L.F.: Selective Shunting in Esophageal Varices. In: Clinical Surgery International Series, Volume 12 (P. Hunt, ed.), Edinburgh, England, Church Hill Livingston, 1986, pp. 105-114.

IV. ABSTRACTS

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IV. ABSTRACTS (Cont'd.)

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9. Holman, J.M., Jr. and Saba, T.M.: Leukocyte Mediated Hepatocyte Injury. J. Leukocyte Biology 40:255, 1986.

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12. Masaki T., Peng, H.W., Terreros, D.A., Holman, J., and Cheung, A.K.: A Rabbit Model of Neointimal Hyperplasia in Native Arteriovenous Fistula (AVF). JASN 10:211A, 1999.

V. PRESENTATIONS

1. "Sepsis in the Management of Complicated Biliary Disorders", Southwestern Surgical Congress, Las Vegas, Nevada, April, 1979.

2. "Reticuloendothelial Function and Biliary Obstruction", Annual Resident Conference, Society of University Surgeons, Houston, Texas, February, 1980.

V. PRESENTATIONS (Cont'd.)

3. "Success of Medical and Surgical Management of Acute Variceal Hemorrhage", Southwestern Surgical Congress, Colorado Springs, Colorado, May, 1980.

4. "Peritoneojugular Shunting for Malignant Ascites", Southwestern Surgical Congress, Monterey, California, May, 1981.

5. "Biliary Obstruction and Host Defense Failure", Association of Academic Surgery, Chicago, Illinois, November, 1981.

6. "Influence of Infusion of Fibronectin Rich Human Cryoprecipitate on Lung Vascular Permeability During Sepsis", FASEB Meetings, Chicago, Illinois, April, 1982.

7. "Effect of Post-Operative Sepsis on Cardiovascular Hemodynamics and Lung Protein Clearance in Sheep During Fibronectin Deficiency", Sixth Annual Conference on Shock, Jackson Hole, Wyoming, June, 1983.

8. "Coexistence of Hepatic and Kupffer Cell Dysfunction During Post-Operative Sepsis", FASEB Meetings, St. Louis, Missouri, April, 1984.

9. "Opsonic Activity of Purified Human Plasma Fibronectin After Infusion Into Post-Operative Septic Sheep", Seventh Annual Conference on Shock, Toronto, Canada, June, 1984.

10. "Effect of Human Plasma Cryoprecipitate on Fluid Resuscitation Requirements of Post-Operative Septic Sheep", Forty-Sixth Annual Meeting and Sixth Tripartate Meeting of Society of University Surgeons, Boston, Massachusetts, February, 1985.

11. "Hepatocyte Injury During Post-Operative Sepsis: Its Relationship to Kupffer Cell Particulate Ingestion", American Association for the Study of Liver Diseases, Chicago, Illinois, November, 1985.

12. "Effect of Bacterial Sepsis on Gluconeogenic Capacity in the Rat", Association of Academic Surgery, Cincinnati, Ohio, November, 1985.

13. "Leukocyte Mediated Hepatocyte Injury", Reticuloendothelial Society, Denver, Colorado, September, 1986.

14. "Effect of Cyclosporine on Reticuloendothelial Phagocytic Activity", Society of Leukocyte Biology, Marco Island, Florida, October, 1989.

V. PRESENTATIONS (Cont'd.)

15. "Inductive OKT3 Therapy Overlapping Early Cyclosporine (CSA) Therapy in Cadaveric Renal Allograft Recipients", American Society of Transplant Physicians, Chicago, Illinois, June, 1991.

16. "Effect of Pentoxifylline (PTF) on T Cell Activation", Western Association of Transplant Surgeons, Maui, Lahaina, Hawaii, March, 1994.